ISoOR Accreditation Pathway for Organoid Biobanks (ISoOR-ISOB)

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Introduction

The ISoOR Accreditation Pathway for Organoid Biobanks (ISoOR-ISOB) provides a structured framework for the assessment and accreditation of organoid biobanks. The ISoOR Accreditation Body (ISoOR-AB) is an independent organization that directly evaluates organoid biobanks through qualified assessors using a methodology guided by the principles of ISO/IEC 17011, including competence, impartiality, consistency, and transparency.

ISoOR-AB conducts assessments to verify that organoid biobanks operate according to internationally recognized best practices in quality management, biosafety, ethics, traceability, and data governance. When appropriate, ISoOR-AB may engage external subject matter experts or independent Conformity Assessment Bodies (CABs) to provide additional technical expertise or reinforce confidence in assessment outcomes; however, such involvement is optional and does not constitute a requirement for accreditation decisions.

Follow these seven steps to achieve ISoOR-ISOB accreditation.

Accreditation Pathway

1. Eligibility Check

Confirm that your organoid biobank meets the foundational requirements for accreditation.

Legal Status

Ensure that your biobank is legally established and authorized to operate in accordance with applicable national laws and regulations.

Compliance

Verify adherence to relevant national and international requirements.

Biosafety

Follow applicable regulations and recognized best practices for the safe handling, processing, storage, and distribution of biological materials, including organoids.

Ethics

Obtain approvals from the appropriate Institutional Review Board (IRB), Ethics Committee, or equivalent authority for activities involving human-derived materials, ensuring compliance with ethical and legal requirements.

Data Governance

Implement secure and traceable systems for data management, ensuring protection of donor privacy, confidentiality, and sample-associated information.

Biobanking Standards

Align operations with internationally recognized biobanking principles and best practices, including procedures for tissue acquisition, organoid derivation, quality control, cryopreservation, storage, traceability, and distribution.

Action

Conduct a self-assessment using the ISoOR-ISOB checklists available through ISoOR-AB to evaluate readiness. Address any identified gaps in documentation, facilities, personnel competence, training, or quality management before submitting an application.

2. Application Submission

Submit a formal application to ISoOR-AB for assessment and accreditation.

Required Documents

Completed ISoOR-ISOB Pre-Assessment Questionnaire

The questionnaire shall include the following information:

General Institutional Information

- Institution name and legal registration.
- Mission and organizational structure.
- Key contact person.
- Scope of organoid research and biobanking activities.
- Collaborations and funding sources.

Organoid Workflows

Tissue Acquisition and Donor Management

- Source of tissues.
- Ethical protocols and consent procedures.
- Donor metadata and sample handling procedures.

Tissue Processing and Organoid Initiation

- Tissue dissociation methods.
- Embedding techniques.
- Culture conditions and medium composition.
- Incubation parameters.

Organoid Expansion and Passaging

- Culture monitoring procedures.
- Passaging methods.
- Batch tracking and contamination controls.

Characterization and Quality Control

- Phenotypic, genotypic, and functional assays.
- Acceptance criteria and quality metrics.

Cryopreservation and Storage

- Freezing and recovery procedures.
- Storage formats.
- Monitoring, alarm systems, and contingency measures.

Distribution and Use

- Material approval procedures.
- Packaging and shipping practices.
- Data-sharing policies.
- Post-distribution follow-up procedures.

Data Management

- Laboratory Information Management Systems (LIMS), where applicable.
- Linkage of samples and associated metadata.
- Backup procedures and data security measures.

Facilities and Equipment

Provide information regarding:

- Laboratory layout and workflow segregation.

- Environmental and climate control systems.
- Essential equipment and infrastructure.
- Environmental monitoring procedures.
- Equipment maintenance and calibration programs.

Personnel Structure and Competence

Provide information concerning:

- Roles and responsibilities.
- Education and qualifications.
- Training records.
- Continuing education and competency maintenance programs.

Standard Operating Procedures (SOPs)

Submit procedures covering:

- Tissue processing and organoid derivation.
- Expansion and passaging.
- Cryopreservation and storage.
- Quality control activities.
- Data management and traceability.
- Document control and periodic review.

Ethical and Consent Framework

Provide documentation concerning:

- Ethics committee or IRB approvals.
- Consent procedures and consent models.
- Compliance with national regulations and international guidelines.

Data Management and Traceability Systems

Describe:

- Data categories and records maintained.
- Chain-of-custody procedures.
- Backup and recovery protocols.
- Data security measures.
- Audit trail mechanisms.

Quality Management Documentation

Submit a Quality Manual or equivalent documentation describing:

- Quality objectives.
- Risk management processes.
- Internal audits.
- Corrective and preventive actions.
- Continuous improvement activities.

Submission Process

Applicants shall:

- Submit all documentation electronically through the ISoOR-AB online portal or by email.
- Provide hard copies when specifically requested by ISoOR-AB.
- Define the scope of accreditation requested, including activities such as organoid derivation, expansion, storage, characterization, distribution, or related services.

Action

Register with ISoOR-AB, pay the applicable application fee, and submit the required documentation within six months following completion of the eligibility review. Ensure that all procedures and supporting documents are complete, current, and sufficiently detailed to facilitate the assessment process.

3. Documentation Review

ISoOR-AB shall conduct a review of the submitted documentation to determine whether the applicant's organoid biobank is prepared to proceed to the on-site assessment stage.

Focus Areas

Standard Operating Procedures (SOPs)

Evaluate whether procedures governing organoid acquisition, processing, culture, quality control, cryopreservation, storage, distribution, and data management are adequately documented and consistent with internationally recognized biobanking principles.

Personnel Competence and Training

Confirm that personnel possess appropriate qualifications, training, and competency for organoid-related activities, biosafety practices, and quality management responsibilities.

Ethics and Regulatory Compliance

Verify that ethics approvals, informed consent procedures, and associated documentation comply with applicable laws, regulations, and internationally recognized ethical principles.

Biosafety and Biosecurity

Assess whether facilities, procedures, and risk management measures provide appropriate protection for personnel, biological materials, and the environment.

Data Management and Traceability Systems

Evaluate the integrity, security, traceability, and confidentiality of records, samples, donor-associated information, and electronic systems.

Outcome

- If the documentation review demonstrates adequate readiness, the application proceeds to the on-site assessment stage.
- If deficiencies are identified, ISoOR-AB may issue one or more Corrective Action Requests (CARs), specifying the findings and the required actions.
- Applicants are normally provided up to three months to address deficiencies unless an alternative timeframe is established by ISoOR-AB.

Action

Respond promptly to all Corrective Action Requests (CARs), revise affected procedures or records as necessary, and submit supporting evidence through the ISoOR-AB portal or by email for review.

4. On-Site Assessment

ISoOR-AB shall appoint a qualified assessment team to conduct an on-site evaluation of the organoid biobank and verify the effective implementation of documented processes. Assessment teams are normally composed of ISoOR-AB assessors and may include external subject matter experts or independent Conformity Assessment Bodies (CABs), when deemed appropriate, to provide additional technical expertise or reinforce confidence in assessment outcomes.

Assessment Scope

The assessment may include:

- Observation of organoid workflows, including tissue acquisition, derivation, expansion, characterization, cryopreservation, storage, distribution, and associated quality control activities.
- Verification of sample traceability systems, including labeling, barcoding, and Laboratory Information Management Systems (LIMS), where applicable.
- Evaluation of biosafety and biosecurity measures, including laboratory practices, environmental controls, and protective equipment.
- Verification of personnel competence through interviews, training records, and demonstration of technical activities.
- Inspection of equipment maintenance, calibration, qualification, and monitoring programs.
- Assessment of data management systems, information security, and compliance with applicable privacy and confidentiality requirements.

Assessment Process

The on-site assessment normally includes:

- Opening and closing meetings.
- Review and sampling of records and documents.
- Facility inspections and observation of activities.
- Interviews with personnel.
- Evaluation of implementation and effectiveness of the quality management system.

Findings may be classified as:

- Major nonconformities, representing systemic deficiencies that may affect the integrity or reliability of biobank operations.
- Minor nonconformities, representing isolated issues that do not compromise overall system effectiveness.
- Opportunities for improvement, which do not constitute nonconformities but may enhance quality and performance.

Corrective actions are typically required within 30 to 90 days, depending on the significance of the findings.

Duration

The duration of the on-site assessment is generally between two and five days, depending on the size, complexity, scope, and operational maturity of the organoid biobank.

Action

Prepare personnel for interviews and demonstrations, ensure that equipment maintenance and calibration records are current, and organize documentation and records to facilitate efficient assessment activities.

5. Accreditation Decision

Following completion of the on-site assessment and review of any corrective actions, ISoOR-AB shall evaluate the assessment findings and issue an accreditation decision.

Possible Outcomes

Full Accreditation

Full accreditation is granted when the organoid biobank demonstrates conformity with ISoOR-ISOB requirements and any identified major nonconformities have been satisfactorily resolved.

- Accreditation is valid for three years.
- Accredited organizations receive an official ISoOR-ISOB Certificate and registration number.
- Continued accreditation is subject to ongoing surveillance and periodic reassessment.

Provisional Accreditation

Provisional accreditation may be granted when minor nonconformities remain that do not compromise the integrity, safety, or effectiveness of the biobank's operations.

- Corrective actions shall normally be completed within three to six months.
- Continued accreditation status is subject to successful verification of corrective actions through document review or follow-up assessment.

Denial of Accreditation

Accreditation may be denied when significant deficiencies or unresolved major nonconformities prevent demonstration of conformity with ISoOR-ISOB requirements.

- ISoOR-AB shall provide documented findings and recommendations.
- Applicants may reapply after addressing the identified deficiencies, normally after a minimum period of six months.

Decision Process

ISoOR-AB shall review:

- Documentation review findings.
- On-site assessment reports.
- Corrective actions and supporting evidence.
- Recommendations from the assessment team.

Accreditation decisions shall be made independently and impartially to ensure consistency and alignment with internationally recognized biobanking principles and best practices.

Action

Respond promptly to any outstanding nonconformities and submit supporting evidence through the ISoOR-AB portal or by email. Following completion of the review process, accreditation certificates are normally issued within one to two months.

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6. Post-Accreditation Monitoring

Accredited organoid biobanks shall maintain continued conformity with ISoOR-ISOB requirements through ongoing monitoring and periodic reassessment.

Annual Self-Assessment

Accredited organizations shall submit an annual report to ISoOR-AB containing updates regarding:

- Standard Operating Procedures (SOPs).
- Internal audits and management reviews.
- Personnel training and competency records.
- Quality indicators and performance metrics, including, where applicable, organoid viability, contamination rates, traceability performance, and corrective actions.

Surveillance Assessments

ISoOR-AB conducts periodic surveillance activities to verify continued conformity and effective implementation of the quality system.

These activities may include:

- Remote assessments.
- On-site assessments.
- Targeted reviews of specific processes.
- Follow-up assessments related to previous findings.

ISoOR-AB may conduct unannounced assessments when necessary to ensure the integrity and credibility of the accreditation program.

Reaccreditation

A comprehensive reassessment shall normally be conducted every three years, following the requirements described in Steps 2 through 5.

Suspension or Withdrawal of Accreditation

Failure to maintain conformity with ISoOR-ISOB requirements may result in:

- Suspension of accreditation.
- Reduction of scope.
- Withdrawal of accreditation.

Corrective actions and additional assessments may be required before accreditation can be restored.

Action

Assign appropriate personnel to oversee quality management and continual improvement activities. Submit annual reports within the timelines established by ISoOR-AB and maintain readiness for surveillance and reaccreditation assessments.

7. Recognition and Benefits

ISoOR-ISOB accreditation demonstrates a commitment to quality, traceability, ethical practices, biosafety, and continual improvement, providing accredited organoid biobanks with increased visibility and opportunities for collaboration within the scientific and biomedical communities.

Certificates and Registry

Accredited organizations receive:

- An official ISoOR-ISOB Certificate with a unique registration number.
- Inclusion in the ISoOR International Registry of Accredited Organoid Biobanks.
- Authorization to reference ISoOR-ISOB accreditation and use applicable logos and marks in accordance with ISoOR policies.

Benefits

Enhanced Credibility and Visibility

ISoOR-ISOB accreditation demonstrates that the biobank operates according to internationally recognized principles and best practices for organoid biobanking, increasing confidence among researchers, healthcare institutions, industry partners, and funding organizations.

Strengthened Collaboration Opportunities

Accreditation may facilitate scientific and commercial collaborations with universities, hospitals, biotechnology companies, pharmaceutical organizations, and research institutes involved in disease modeling, drug development, regenerative medicine, and personalized medicine.

Competitive Advantage

Accredited biobanks can demonstrate their commitment to quality, traceability, and ethical governance, enhancing their reputation and supporting participation in collaborative projects and scientific initiatives.

Support for Funding and Research Programs

Compliance with recognized quality frameworks may strengthen applications for grants and collaborative programs where quality assurance and standardized practices are considered during evaluation.

Action

Promote accreditation status through scientific publications, websites, and professional communications, and actively participate in ISoOR initiatives, educational activities, and networking opportunities.

Additional Notes

Timeline

Applicants should anticipate approximately 6 to 12 months from application submission to accreditation, depending on the scope and complexity of operations, responsiveness to corrective actions, and scheduling of assessments.

Accredited organizations are subject to annual reporting requirements and comprehensive reassessment every three years.

Costs

ISoOR-AB fees may include:

- Application fees.
- Documentation review fees.
- On-site assessment fees.
- Surveillance and reassessment fees.

Applicants should also consider resources required for personnel training, documentation, infrastructure improvements, and quality management activities.

Resources

ISoOR-AB provides guidance documents, checklists, templates, and educational resources to support applicants throughout the accreditation process.

Recommendations

1. Perform a Thorough Self-Assessment

Use ISoOR-ISOB checklists to identify deficiencies related to procedures, ethics, biosafety, facilities, quality systems, and data management.

2. Develop Robust Documentation

Prepare a comprehensive Quality Manual and maintain current Standard Operating Procedures for all critical activities. Obtain ethical approvals and regulatory authorizations early in the process.

3. Prepare for the On-Site Assessment

Train personnel on quality and biosafety requirements, ensure equipment calibration and maintenance records are current, and verify the effectiveness of traceability systems before the assessment.

4. Promote Continual Improvement

Establish mechanisms for internal audits, management review, corrective actions, risk management, and ongoing personnel development to maintain long-term conformity.

5. Engage with the ISoOR Community

Participate in ISoOR educational programs, scientific meetings, and networking activities to exchange knowledge and promote accredited status.

6. Contact ISoOR-AB

Visit the ISoOR-AB website for application forms, guidance documents, and accreditation resources. Applicants may contact the Accreditation Committee for technical guidance regarding the accreditation process.

ISoOR-ISOB Accreditation Required Documents

Applicants shall provide the following documentation:

- ISoOR-ISOB Pre-Assessment Questionnaire.
- Description of the scope of the biobank's activities (PDF format).

- ISoOR-AB Self-Assessment Checklist.
- Quality Manual or equivalent quality management documentation.
- Standard Operating Procedures (SOPs) and supporting records, as applicable.
- Ethics approvals and informed consent documentation, where applicable.
- Additional documents requested by ISoOR-AB during the assessment process.

Actions

- Proceed with payment of the application fee.
- Submit the required documents through the ISoOR-AB portal or by email.
- Maintain communication with ISoOR-AB throughout the documentation review and assessment process.

Additional Notes for Mainland China

Organoid biobanks operating in Mainland China shall comply with all applicable national laws, regulations, and technical standards governing biosafety, biosecurity, ethics, human genetic resources, data management, and biomedical research.

Relevant regulatory frameworks may include, but are not limited to:

- Biosafety Law of the People's Republic of China (2020).
- Regulations on the Administration of Human Genetic Resources (2019, as amended).
- Regulations on Biosafety Management of Pathogenic Microorganism Laboratories.
- Applicable national standards and technical specifications relating to laboratory biosafety, specimen handling, and quality management.

Special attention should be given to:

- Ethical review and informed consent requirements for human-derived materials.
- Human Genetic Resources (HGR) regulations.
- Biosafety and waste management requirements.
- Protection of personal information and data security.
- Requirements established by national, provincial, and institutional authorities.

ISoOR-ISOB accreditation does not replace legal or regulatory obligations. Applicants are responsible for ensuring compliance with all applicable laws and requirements in their jurisdiction.

Internationally recognized guidance documents and best practices, including those issued by WHO, ISBER, OECD, and other relevant organizations, may be used to support harmonization and promote international compatibility of organoid biobanking practices.

Conformity with ISoOR-ISOB requirements is evaluated through documentation review, on-site assessments, surveillance activities, and periodic reassessment, with particular attention to quality management, biosafety, ethical governance, traceability, and data integrity.